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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,685	11/21/2000	Eugeni A. Vaisberg	CYTOP007C2	5849

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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/14/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding!

Office Action Summary

Application No.

09/718,685

Applicant(s)

VAISBERG ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-43, 45, 51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-43, 45, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments in Paper No. 15, filed 13 March 2003, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 40-43, 45, 51, and 52 (new). Claims 1-39, 44, and 46-50 are cancelled according to Paper No. 15, filed 13 March 2003.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claim 52 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The introduction of a "fingerprint implementation scheme" new claim 52 in Paper No. 15, filed 13 March 2003, is considered new matter. The "fingerprint implementation scheme" is considered a general broad scheme, and therefore encompasses scheme(s) not previously

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disclosed/found in the original specification. Additionally, applicants failed to provide support for new claim 52. Therefore, the introduction of “fingerprint implementation scheme” is considered NEW MATTER as it is not considered to be limited to the particular algorithm (pages 44-45; and Appendix B) exemplified.

SCOPE OF ENABLEMENT

For reasons of record the rejection of claims 40-43, 45, 51, and 52 (new) under 35 U.S.C. § 112, first paragraph, are maintained. Additional, clarification as to the basis of the rejection is presented.

Applicants argue “an incorrect standard in evaluating whether undue experimentation” has been applied. That such standard suggests that considerable experimentation will be required to identify the morphological values.

It is acknowledged that the process of manipulating the cells, imaging the cells, and analyzing the images were routine at the time of the invention and the morphological values, as in claim 40, lines 15-20. For clarification the rejection is directed to claim 40, particularly lines 9-11 and 16 which states “code for producing a statistical profile of said manipulated cells by combining the morphological values or degrees of presence of said morphological values in said plurality of different cell lines whereby a statistical profile of said manipulated cells is produced...” and “...morphological value is one or any combination of...”. It is the computational/algorithm aspect of “combining” the morphological values or degrees of presence and thereby deriving the morphological values (i.e. from cell components) and utilizing said value to produce a statistical profile that is limited in scope by the original disclosure (pages 34-45 of the Specification).

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The following is reiterated from the previous office action:

“...the specification fails to provide for other means by which to derive a morphological value, for example, “cell count and optical density” to derive a morphological value (instant claim 40, lines 9-20). The claims are not limited to a fingerprint implementation for a morphological value derived from combinations of cell attributes. The specification teaches only a fingerprint as a value for these combinations. Although not represented in instant claims the “degrees of presence of said morphological values” is by arranging/assigning resulting measurement into a string of numbers and reduced to a pseudo-nucleic acid sequence such arrangement/assignment is not represented in the in claims (page 45, lines 18-23 of the Specification).”

Thus, the instant claims embrace more than what is taught in the original disclosure.

Again no other methods of deriving a morphological value are disclosed. None appear to have been known in the art. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known practice how to the claimed invention commensurate in scope with the claims.

ACTION IS FINAL AS NECESSITATED BY AMENDMENT

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

May 7, 2003

Examiner Initials:

CSM

Marianne P. Allen
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PRIMARY EXAMINER
GROUP 1200
141631